IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NEW YORK

BIOFER S.P.A., Plaintiff, v. VIFOR (INTERNATIONAL) AG, Defendant.	Civil Action No. 1:22-CV-02180-AMD-SJB

PLAINTIFF BIOFER'S OPENING CLAIM CONSTRUCTION BRIEF

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Pursuant to Local Patent Rule 12(a), Plaintiff Biofer S.p.A ("Biofer" or "Plaintiff") submits this Opening Claim Construction Brief with its proposed construction of the disputed claim language of United States Patent No. 8,759,320 ("the '320 patent" or "Asserted Patent") (Ex. 1[1]). In support thereof, Biofer also submits intrinsic and extrinsic evidence including declarations from technical experts Dr. Paul J. Chirik ("Chirik Decl.") and Dr. Allan S. Myerson ("Myerson Decl.").

I. INTRODUCTION

It is well established that patent claim construction is a matter of law for the court. *Markman v. Westview Instruments Inc.*, 517 U.S. 370, 388-89 (1996). Patent claims should be construed as one having ordinary skill in the art ("a POSA") would understand them based on the patent's claims and specification, as well as the record of the proceedings before the United States Patent Office ("USPTO") leading to allowance of the application as an issued U.S. patent ("the file history" or "prosecution history"). *Phillips v. AWH Corp*., 415 F.3d 1303, 1312-13 (Fed. Cir. 2005) (en banc).

The first of the two claim terms in dispute ("stoichiometric quantity") is readily interpreted in accordance with its plain and ordinary meaning to a POSA. Biofer's proposed construction follows that plain and ordinary meaning, and is fully supported by the claim language, specification, and prosecution history. Similarly, Biofer's proposed construction of the second disputed claim term ("pH between 7.0 and 9.0") tracks how the patentee expressly defined that claim language during prosecution before the USPTO, and is fully consistent with the patent.

Defendant Vifor, on the other hand, after affirmatively arguing for the "plain and ordinary meaning" of both disputed terms in a recent IPR proceeding before the USPTO, now seeks to have

[1] All Exhibits are attached to the Declaration of Benjamin Witte ("Witte Decl."), submitted concurrently herewith, unless otherwise noted.

this Court read multiple unstated limitations (from the patent specification or otherwise)—including so-called "mathematical precision"[2]—into the broad unencumbered language of the claims. This restrictive approach conflicts with controlling legal principles of claim construction and is inconsistent with the intrinsic record. Accordingly, Biofer respectfully submits that its proposed constructions should be adopted by the Court.

II. NATURE AND STAGE OF THE PROCEEDINGS

On April 15, 2022, Biofer filed this lawsuit against Vifor (International) AG ("Vifor" or "Defendant") alleging infringement of the '320 patent based on Vifor's manufacturing process for the accused Injectafer® product and/or its ferric carboxymaltose active pharmaceutical ingredient ("API") contained therein. (D.I. 1 at ¶ 1.)

On September 30, 2022, Vifor filed a 70-page petition for *inter partes* review (the "IPR") (Ex. 2) challenging the validity of the '320 patent before the USPTO's Patent Trial and Appeal Board ("PTAB"), that was accompanied by forty-five (45) exhibits including an 83-page expert declaration from Dr. Jeffrey Winkler ("Winkler Decl.") (Ex. 3). Shortly thereafter, this Court entered a Scheduling Order (D.I. 27) on October 6, 2022, pursuant to which Biofer served a 43-page set of Initial Infringement Contentions (on February 24, 2023) asserting infringement of claims 1-16, 19-21 and 23-25 of the '320 patent ("Asserted Claims"). Biofer also filed an opposition to Vifor's IPR on January 30, 2023.

Defendant Vifor served its Initial Invalidity Contentions on April 14, 2023, which expressly adopted and incorporated the same claim construction and prior art invalidity positions

[2] Biofer's understanding of Vifor's claim construction positions is based on the parties' meet and confer videoconference on May 3, 2023 and related emails. In those communications, Vifor confirmed that its proposed construction required 1:1 "mathematical precision" and that proposal was not the plain and ordinary meaning. (*See* Ex. 6.)

argued in the IPR. (Ex. 4 at, *e.g.*, 10 ("Vifor incorporates in its entirety, as though fully set forth herein, Vifor's Petition" and "all accompanying exhibits").) Then, on April 24, 2023, the USPTO issued a decision denying Vifor's IPR Petition because Vifor had failed to establish a reasonable likelihood of proving the invalidity of any of the claims of the '320 patent. (Ex. 5 at, *e.g.*, 13-14.) Prior to losing the IPR, Vifor's only non-infringement argument was based on the claimed pH range. After losing the IPR, however, Vifor amended its interrogatory responses to add new non-infringement arguments, including based on the stoichiometric limitation.

With respect to claim construction, in compliance with the Court's Local Patent Rules and requirements, the parties met and conferred on claim construction issues/terms by videoconference and email, and jointly provided a Claim Construction Chart that identifies the terms in dispute from the '320 patent. (D.I. 44.) Biofer hereby submits this Opening Brief in support of its positions on the disputed terms. A claim construction hearing is scheduled for August 3, 2023.

Fact discovery is scheduled to end on September 29, 2023. Expert discovery is scheduled to end on March 8, 2024. A trial date has not yet been scheduled.

III. ARGUMENT

A. THE GOVERNING LEGAL PRINCIPLES OF CLAIM CONSTRUCTION

1. Patents, Claims and the General Rules of Construction

A patent is a formal legal document, on an invention, that is typically divided into two main parts. First, there is a written description, referred to as the patent specification, which illustrates and explains how to practice the invention. Next, there are claims at the end of the specification which define the scope of the invention. Using the '320 patent as representative, it includes a specification (Ex. 1 at column 1, line 1 to column 16, line 41 (*i.e.*, 1:1-16:41)) and 25 claims (*id.* at 16:44-18:29).

All claims include a recitation of elements commonly known as "limitations." They are

called limitations because the scope or breadth of the claim is limited in the sense that the accused process/product, to be an infringement of the claim, must include every limitation recited in the claims (either literally or under the doctrine of equivalents). Claims may be independent or dependent. The scope of an independent claim is commensurate with the limitations or words recited in the claim. For example, claim 1 of the '320 patent is an independent claim. A dependent claim includes all the limitations of the independent claim (and the other claims from which it depends), as well as the additional limitation(s) recited in the dependent claim. For example, claims 2-25 of the '320 patent are dependent claims.

Patents are issued as a result of a patent application being submitted by the inventor(s) to the USPTO and being reviewed by a trained USPTO Examiner. Typically, the examination process involves communications between the applicant(s) and the Examiner, addressing the scope and patentability of the patent claims in light of the prior art. These communications form the official record of the application and are commonly referred to as the "prosecution" or "file" history.

As stated above, claim construction is a question of law to be determined by the Court. *Markman*., 517 U.S. at 372. The Court should give the disputed terms their "ordinary and customary meaning as understood by a person of ordinary skill in the art at the time of invention." *Phillips v. AWH Corp*., 415 F.3d 1303, 1312-13 (Fed. Cir. 2005) (en banc). Two different forms of evidence are considered during claim-construction: intrinsic evidence, which generally consists of the claims, specification, and prosecution history; and extrinsic evidence, which comprises materials that are not part of the asserted patent's public record. *Id.* at 1314-17. As the Federal Circuit has repeatedly confirmed, the intrinsic record is given primacy in the analysis. *Id*. at 1317; *Power Integrations, Inc. v. Fairchild Semi. Int'l, Inc*., 711 F.3d 1348, 1360 (Fed. Cir. 2013); *Kara Tech. Inc. v. Stamps.com Inc.,* 582 F.3d 1341, 1348 (Fed. Cir. 2009) ("While helpful, extrinsic

sources like expert testimony cannot overcome more persuasive intrinsic evidence.") That said, district courts are "authorized . . . to rely on extrinsic evidence, which 'consists of all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises." *Phillips,* 415 F.3d at 1317-18.

2. Claim Language and Its Ordinary Meaning

In general, the first step in claim construction is to consider the language of the patent claim. *Markman*, 517 U.S. at 1314; *Mantech Envtl. Corp. v. Hudson Envtl. Servs. Inc.*, 152 F.3d 1368. 1373 (Fed. Cir. 1998) ("under proper claim construction methodology, we look first to the language of the claims"). Claim terms should not be given a construction different from their plain meaning absent some clear reason to do so. *Johnson Worldwide Assoc., Inc. v. Zebco Corp.*, 175 F.3d 986, 989-90 (Fed. Cir. 1999); *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1327 (Fed. Cir. 2003) ("[W]e indulge a heavy presumption that a claim term carries its ordinary and customary meaning").

A patent claim is also not to be treated "like a nose of wax, which may be turned and twisted in any direction, by merely referring to the specification, so as to make it include something more than, or something different from, what its words express." *White v. Dunbar,* 119 U.S. 47, 51 (1886). For instance, a patent claim may not be twisted one way in an attempt to avoid infringement and another to find invalidity. *See, e.g., Ramot at Tel Aviv Univ. Ltd. v. Cisco Sys., Inc*., No. 2:19-CV-00225-JRG, 2020 WL 2517581, at *12 (E.D. Tex. May 15, 2020) (rejecting as "not credible" and "not justified" Defendant's "nose-of-wax approach to claim construction" where Defendant had "affirmatively presented 'plain and ordinary meaning' as the as the proper construction" for purposes of invalidity in a prior IPR proceeding, but then inconsistently argued for a narrower construction before the district court).

3. The Patent Specification/Written Description

Next, although claims should be read in light of the specification, they should not be limited to the preferred embodiment or specific examples disclosed therein. *Markman*, 517 U.S. at 1315-17; *Tate Access Floors, Inc. v. Maxcess Technologies, Inc.*, 222 F.3d 958, 966 (Fed. Cir. 2000).[3] Indeed, claims—not specifications—are infringed. *SRI Int'l v. Matsushita Elec. Corp. of America*, 775 F.2d 1107, 1121-22 (Fed. Cir. 1985) ("If everything in the specification were required to be read into the claims, … there would be no need for claims.")

As a logical corollary to the above legal precepts, claims may not be construed by reading in extraneous words not actually contained in the claim. *Phillips*, 415 F.3d at 1319-20 (describing importation of limitations from the specification into the claims as a "cardinal sin" of patent law); *Laitram Corp. v. NEC Corp.*, 163 F.3d 1342, 1347 (Fed. Cir. 1998) ("[A] court may not import limitations from the written description into the claims."). Unrecited adjectives, modifiers, and other limiting descriptors or verbiage not actually in the claims are not to be added from the specification to limit claim recitations. *Burke, Inc. v. Bruno Indep. Living Aids, Inc.*, 183 F.3d 1334, 1340-41 (Fed. Cir. 1999); *Johnson Worldwide*, 175 F.3d at 989; *Specialty Composites*, 845 F.2d at 987 ("plasticizer" not limited to "external plasticizer").

4. The Prosecution History

A patent's prosecution history can also be a meaningful intrinsic tool of claim construction. *Markman*, 517 U.S. at 1317. It is most relevant in cases where the inventor either defines, or disavows, the meaning of a claim term during prosecution. *See, e.g., Tempo Lighting, Inc. v. Tivoli,*

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[3] "What is patented is not restricted to the examples, but is defined by the words in the claims if those claims are supported by the specification…. Where a specification does not require a limitation, that limitation should not be read from the specification into the claims." *Specialty Composites v. Cabot Corp*., 845 F.2d 981, 987 (Fed. Cir. 1988).

LLC, 742 F.3d 973, 977 (Fed. Cir. 2014) (affirming construction "inert to light" where applicant defined it in the prosecution history); *TecSec, Inc. v. Int'l Bus. Machines Corp*., 731 F.3d 1336, 1344 (Fed. Cir. 2013) (affirming construction because applicant "defined the term during prosecution"); *Honeywell Int'l, Inc. v. Universal Avionics Sys. Corp*., 493 F.3d 1358, 1364 (Fed. Cir. 2007) (affirming construction where to hold otherwise "would ignore the patentees' definition of the term 'heading' and their consistent use of that term throughout the prosecution history"); *see also Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 980 (Fed. Cir. 1995) (en banc), *aff'd* 517 U.S. 370 (1996) (the "avowed understanding of a patentee, expressed by him, or on his behalf" can aid in understanding the meaning of claim terms and confirm their construction).[4]

The Federal Circuit has acknowledged that divergence from the plain meaning is permissible in situations where "a patentee sets out a definition and acts as his own lexicographer" during prosecution or in the patent itself. *Golden Bridge Tech., Inc. v. Apple Inc*., 758 F.3d 1362, 1365 (Fed. Cir. 2014) (citations and quotations omitted); *see also Thorner v. Sony Computer Entm't Am. LLC*, 669 F.3d 1362, 1365 (Fed. Cir. 2012); *Vitronics Corp. v. Conceptronic, Inc*., 90 F.3d 1576, 1582 (Fed. Cir. 1996) ("express representations made by the applicant regarding the scope of the claims" during prosecution are "often of critical significance in determining the meaning of the claims"); *CVI/Beta Ventures, Inc. v. Tura LP*, 112 F.3d 1146, 1158 (Fed. Cir. 1997) ("through statements made during prosecution or reexamination an applicant for a patent or a patent owner, as the case may be, may commit to a particular meaning for a patent term, which meaning is then binding in litigation").

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[4] The standard for finding disavowal is exacting—a so-called "disclaimer" of claim scope must be "clear and unmistakable." *See*, *e.g*., *Bayer AG v. Elan Pharm. Research Corp*., 212 F.3d 1241, 1251 (Fed. Cir. 2000); *see also Grober v. Mako Prod., Inc*., 686 F.3d 1335, 1342 (Fed. Cir. 2012) (disclaimer requires "an unambiguous disavowal").

B. PERSON OF ORDINARY SKILL IN THE ART

Claim terms "are examined through the viewing glass of a person skilled in the art." *Ferguson Beauregard/Logic Controls v. Mega Sys., LLC*, 350 F.3d 1327, 1338 (Fed. Cir. 2003). For the '320 patent, a person or ordinary skill would have at least the equivalent of a Master's degree in chemistry, chemical engineering, pharmacy, pharmaceutics, or a comparable field and at least four years of academic, research, or industry experience related to medicinal chemistry or chemical process development, or a comparable field. The education level of a POSA may be somewhat higher or lower depending on the length of work experience, and vice versa. (*See* Chirik Decl. ¶ 16; Myerson Decl. ¶ 27.)

C. BACKGROUND FACTS

1. BRIEF TECHNICAL BACKGROUND

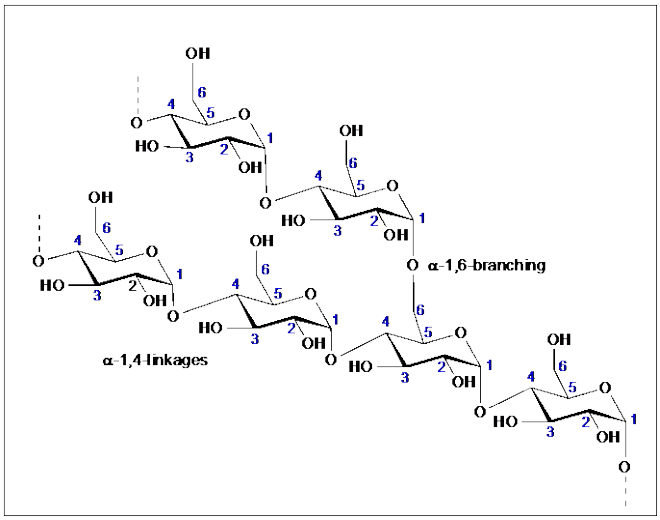
a. Polysaccharides and Stoichiometry

The accompanying declarations of Dr. Chirk and Myerson explain certain aspects of the technology-at-issue.

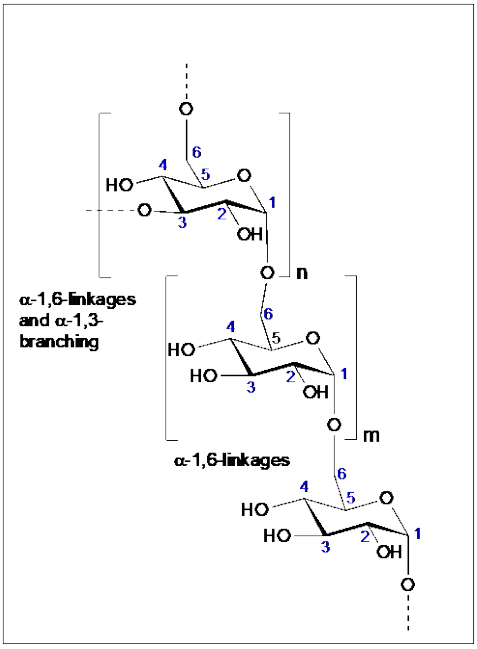
To begin with, a **polysaccharide** is a type of carbohydrate which is a biomolecule composed of carbon, hydrogen, and oxygen atoms. (Chirik Decl. ¶ 18.) Polysaccharides are formed by the joining of many sugar molecules, known as monosaccharides, through glycosidic linkages. (*Id*.) A glycosidic linkage is where two monosaccharides are joined through carbon-oxygen bonds formed by loss of a water molecule. (*Id*.) Polysaccharides have diverse structures that range from relatively simple linear to more complex, highly branched forms. (*Id*.)

A **dextrin** is a type of carbohydrate derived from starches, such as corn, wheat, or potatoes through a process called hydrolysis. (Chirik Decl. ¶ 19.) During the hydrolysis process, the starch molecules are broken into smaller chains of glucose molecules which form dextrin. (*Id*.) Dextrin has a linear or branched structure with α-1,4 and α-1,6 glycosidic linkages between glucose units.

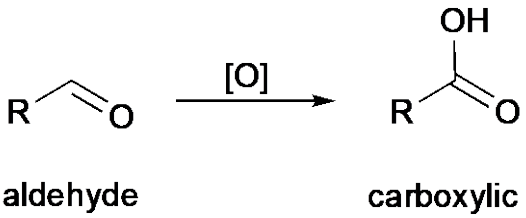
(*Id*.) It may contain reducing or non-reducing end groups depending on the degree of hydrolysis. (*Id*.) The degree of hydrolysis can vary, resulting in dextrins with different molecular weights. (*Id*.) Thus, dextrins (and as discussed further below, dextrans) are not discreet, monodispersed chemical entities. (*Id*.) Rather, they have molecular weight distributions. (*Id*.) The general structure for dextrin-based polymers is shown below:



(*Id*.) Similarly, a **dextran** is a type of polysaccharide that is composed of glucose units connected by α-1,6 glycosidic bonds, with occasional α-1,3 branches. (Chirik Decl. ¶20.) The structure of dextran is highly branched, with the main chain formed by α-1,6 linkages and branches occurring through α-1,3 linkages. (*Id*.) The degree of branching can vary, resulting in dextrans with different molecular weights. (*Id*.) The general structure for dextran-based polymers is shown below:



(*Id.*) An **aldehyde group** is a functional group having an aldehyde moiety (-CHO). (*Id.* at ¶21.) An "end aldehyde group" is an aldehyde group found at the terminal end of a polysaccharide or carbohydrate chain, known as a reducing end. (*Id.*) However, an aldehyde group can also occur in the interior of a molecule, away from the ends. (*Id.*) Both end aldehyde groups and interior aldehyde groups can participate in oxidation reactions. (*Id.*) Oxidation of an aldehyde group refers to a chemical reaction in which the aldehyde (-CHO) undergoes a loss of electrons, *e.g.*, forming a carboxylic acid:



(*Id.*) The **Dextrose equivalent (DE)** is a measure of the degree of hydrolysis, which indicates the percentage of reducing sugars present in the polysaccharide, expressed as dextrose (glucose) equivalents. (Chirik Decl. ¶22; Chirik Ex. D at 1.) A reducing sugar is a sugar that has a free aldehyde group that can be oxidized. (*Id.*) The DE value provides an indication of the average

degree of polymerization and the relative amounts of shorter-chain carbohydrates (dextrins) and glucose in the product. (*Id*.) A POSA would understand how to measure a DE value of a given sample through a laboratory analysis that measures the reducing sugar content of the polysaccharide sample. (Chirik Decl. ¶23.) A higher DE value indicates a higher degree of hydrolysis and a higher concentration of shorter-chain carbohydrates and glucose. (*Id*.) A lower DE value corresponds to a lower degree of hydrolysis and a higher proportion of longer-chain polysaccharides. (*Id*.) The DE value is not an absolute measure of the molecular weight or chain length distribution of the polysaccharide. (*Id*.) It provides a relative measure of the extent of hydrolysis and thus the amount of end aldehyde groups in the polysaccharide. (*Id*.)

b. pH Measurements

pH is defined as the negative logarithm of the hydrogen ion concentration in solution and is a measure of the relative acidity or alkalinity of a solution. (Myerson Decl. ¶ 29; Myerson Ex. D at 4.) A pH of 7 is neutral, while pH's below 7 are increasingly acidic and those above 7 are increasingly basic. (Myerson Decl. ¶ 29; Myerson Ex. D at 5.) pH is generally measured in the laboratory using an electrochemical measurement (potentiometric), measuring the emf created by a chemical reaction, such as that which takes place between metals and dissolved salts. (Myerson Decl. ¶ 30.) Measurement of pH employs a measurement and reference electrode (in modern instruments these are combined in what is known as a combination electrode, which can further include a temperature sensor). (Myerson Decl. ¶ 31; Myerson Ex. D at 5-8.) For optimal pH measurement, the correct electrode must first be selected, and the following criteria must be considered: Chemical composition, homogeneity, temperature, pH range, container size (length and width restrictions). (Myerson Decl. ¶ 32; Myerson Ex. D at e.g., 9 and 40-46.)

2. OVERVIEW OF THE PATENT'S INTRINSIC RECORD

a. The '320 Patent Claims and Specification

The '320 patent describes improved processes for making trivalent iron (Fe3+) complexes for intravenous treatment of anemia in patients. (Ex. 1 at 1:6-18.) The resulting products are "characterized by good physical-chemical stability over time, low toxicity, use safety also by injection and a good bioavailability." (*Id*. at 8:54-59.) The patent describes and claims a multi-step manufacturing process involving, *inter alia*, (i) activating a sugar, (ii) followed by complexation of the activated sugar with an iron compound, and (iii) purification of the iron/sugar complex. (*Id*. at *e.g*., 8:60-67.)

Independent claim 1, which contains both disputed claim terms, recites the initial steps for preparing an activated sugar using certain conditions which together facilitate selective oxidation of the sugar's end aldehyde while avoiding detrimental depolymerizing side reactions:

> 1. A process for the preparation of an activated sugar comprising the step of reacting a sugar having an aldehyde end group with bromine in a solution at a ***pH between 7.0 and 9.0*** with the specific oxidation of the end aldehyde, wherein
>
> i) said sugar is selected from the group consisting of dextrins and dextrans and wherein
>
> ii) said bromine is produced in situ through the addition of a hypochlorite and an alkaline or earth alkaline metal bromide to said solution, ***said hypochlorite being added in stoichiometric quantities with respect to the aldehyde end groups***, wherein said hypochlorite is added instant by instant, such that an excess of hypochlorite in solution is never present.

(*Id*. at 16:44-56.) The dependent Asserted Claims recite additional features of the subsequent steps of oxidation, complexation, purification, and/or stabilization of the product.[5]

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[5] Dependent claims 2-6 and 25 recite additional features of the initial oxidation steps. Dependent claims 7-12, 19-21 and 23 recite subsequent "complexation" steps of combining the activated sugar with an iron (III) salt under specified conditions to form an iron (III)-activated sugar

With respect to the claimed stoichiometric quantity at-issue for the claimed dextrins and dextrans, there is no mention of "mathematical precision" in the patent. On the contrary, the specification instructs a POSA to determine stoichiometry by using "the average molecular weight" or "dextrose-equivalents." (Ex. 1 at 7:22-27.) As discussed further herein, polysaccharides such as dextrins and dextrans are not mono-dispersed chemical entities, meaning that not all molecules in a given sample have the same molecular weight. (Chirik Decl. ¶¶ 19-20, 30.) Thus, these explicit teachings in the patent of using such non-mathematically precise values are consistent with the knowledge and understanding of a POSA. (*Id*. at ¶¶ 21-23, 31.)

Likewise, with respect to the broadly claimed pH range at-issue, the patent generally describes the range in comparably broad terms without mention of the word "interval" or any need that the pH be "maintained":

- "Surprisingly, we have found … sodium hypochlorite at a pH range between 5.0 and 11.0, preferably between 7.0 and 9.0" (Ex. 1 at 6:36-43);
- "The oxidation reaction is controlled through pH adjustment…. Such that the pH is not lowered below 6.0 and the value of 10.0 is not exceeded" (*id*. at 7:5-10);
- "bringing the pH of the solution to a value between 5.0 and 11.0, preferably between 7.0 and 9.0" (*id*. at 9:14-16);
- "bringing the pH of the solution to a value" (*id*. at 10:17-18); and
- "The pH of the activation reaction of the sugar is between 7.0 and 9.0" (*id*. at 10:46-47).

It is only in other parts of the specification where the word "maintain" is used in reference to a preferred embodiment (*id*. at 7:18-22 and 9:22-27), or some of the examples (*e.g*., Examples 1 and 3-7). The specification also refers to certain pH values as encompassing an error range from ±0.2 to ±0.5. (*See, e.g., id*. at 14:37-38 ("at a pH of 10.8±0.2"); 14:31-32 ("the pH is brought to the

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complex. Dependent claims 13-15 relate to purification of the resulting complex. Dependent claims 16 and 24 relate to stabilization.

value of 9.0±0.5"); 14:39-40 ("The cooled solution is brought to pH 6.0±0.5"); 15:11-12 ("the pH value is brought to 11.5±0.2"); 15:18-19 ("pH 11±0.2"); 15:20-21 ("The pH of the solution is brought to the value of 6.0±0.2"); 15:58-59 ("the pH value is brought to 11.5±0.2"); 15:66-67 ("pH 11.5±0.2"); and 16:1-2 ("The pH of the solution is brought to the value of 6.0±0.2").)

b. Pertinent History of Prosecution of the Patent Before the USPTO

The '320 Patent issued from U.S. Patent Application No. 11/908,575, which is the national stage entry of PCT/IB2006/000560, filed on March 14, 2006, and claims priority to foreign application MO2005A0056 filed in Italy on March 15, 2005. The named inventors of the '320 patent are Stefania Sacchi, Mauro Montorsi, and Egidio Marchi. (Ex. 1 at cover.)

The USPTO Examiner diligently evaluated the '320 patent during prosecution, issuing four (4) Office Actions and rejecting the claims as obvious over various prior art references. At no point during the lengthy prosecution history did the Applicants or the Examiner indicate that the "stoichiometric" limitation required mathematical precision. In fact, when discussing prior art which purportedly taught less than "1.2 times" the stoichiometric amount, Applicants did not distinguish based on mathematical precision, but rather on the basis the art involved a different reaction at a different functional group (not the end aldehyde groups). (*See* Chirik Decl. ¶ 33; Chirik Ex. C at BIOFER_00000271-272, BIOFER_00000315, -320.)

Throughout the prosecution history, the Applicants and USPTO Examiner also consistently referred to pH values interchangeably, with and without a decimal point. For example, the Applicants initially submitted claims reciting a pH "between 7.0 to 9.0," then substituted claims reciting a pH "between 7 to 9," and subsequently went back to claims reciting a pH "between 7.0 to 9.0," each time without any indication of a change in claim scope or meaning. (*See* Myerson Ex. C at BIOFER_00000029 ("between 7.0 and 9.0"), BIOFER_00000263 ("between 7 and 9"),

BIOFER_0000350 ("between 7.0 and 9.0"). Likewise, the USPTO Examiner referenced pH values interchangeably, with and without decimal points, in the Reasons for Allowance. (*Id*. at BIOFER_00000441 (referring to the claimed range of "between 7.0 and 9.0" as a "pH range of 7-9"); BIOFER_00000441-442 (referring to pH measurements of 10.0 and 10 interchangeably).)

During prosecution, the Applicants also expressly defined pH values of the claimed range as having a ±0.2 range. Specifically, Applicants submitted the Declaration of Egidio Marchi ("Marchi Declaration") which described experiments comparing the claimed range of the '320 patent (*i.e*., a pH of 7-9) with that of the prior art (*i.e*., pH of 10). (Myerson Ex. C at BIOFER_00000414-422.) The comparative experiments replicated Example 5 of the '320 patent (i) at a "pH of 8.0" which was expressly defined as a "pH between 7.8 and 8.2" (*id*. at ¶ 3), and (ii) at a "pH of 10.0" which was expressly defined as a "pH between 9.8 and 10.2" (*id*. at ¶ 4):

> 3. Experiment 1 - Example 5 of the patent-in-suit was repeated at a pH of 8.0. 35g of Maltodextrin (MDP003PA12, DE:19.5) are dissolved in 100mL of de-ionized water, and to the obtained solution, 700mg of NaBr are added. The resulting pH amounts to 5.0. The solution is cooled to 15°C and the pH is adjusted to a value of 8.0 with NaOH 30% (w/w). Sodium hypochlorite (11.72% w/w active chlorine, 22.93g, 1eq) is slowly added over 2h maintaining the pH between 7.8 and 8.2 with NaOH 30% (w/w). At the end of the addition, the solution is kept under stirring for 30 min and then an aliquot thereof is dialyzed. "MDP1EQPH8" (see GPC Analysis description).
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> 4. Experiment 2 - Example 5 of the patent-in-suit was repeated at a pH of 10.0. 35g of Maltodextrin (MDP003PA12, DE:19.5) are dissolved in 100mL of de-ionized water and to the obtained solution 700mg of NaBr are added. The resulting pH amounts to 5.0. The solution is cooled to 15°C and the pH is adjusted to a value of 10.0 with NaOH 30%.w/w). Sodium hypochlorite (11.72% w/w active chlorine, 22.93g, 1eq) is slowly added over 2h maintaining the pH between 9.8 and 10.2 with NaOH 30% (w/w). At the end of the addition, the solution is kept under stirring for 30 min and then an aliquot thereof is dialyzed. "MDP1EQPH10" (see GPC Analysis description).

(Myerson Ex. C at BIOFER_00000415.) The results of the experiments, analyzed using gel permeation chromatograph, demonstrated that a higher pH of 9.8 to 10.2 led to increased depolymerization. (*Id*. at ¶ 5-6; *see also* Myerson Decl. ¶¶ 36-37.) Ultimately,

the Examiner found the claims allowable in part based on the Marchi Declaration's showing of the "criticality of the conditions used in the instant process." (Myerson Ex. C at BIOFER_00000442; *see also* Myerson Decl. ¶ 37.)

c. Defendant's Unsuccessful IPR Patent Invalidity Challenge

As indicated above, after being sued for patent infringement in this lawsuit, Vifor unsuccessfully attempted to invalidate the claims of the '320 patent by filing an IPR with the USPTO on September 30, 2022. In its IPR petition, Vifor challenged all of the Asserted Claims of the '320 patent but identified only one term for construction.[6] Regarding all other claim terms, including the stoichiometric and pH terms at issue, Vifor and its expert Dr. Winkler affirmatively argued they would be understood by a POSA to have their "plain and ordinary meaning," including for purposes of claim construction in district court litigation. (*See* Ex. 2 at 16 ("Petitioner's proposed constructions represent the ***plain and ordinary meaning*** that a POSA would assign to the claim terms, which are ***the same constructions that would be appropriate in district court litigation***") (emphasis added); Ex. 3 at ¶ 37 ("I have reviewed the claims of the '320 patent and believe that a POSA would understand each of the other claim terms to have their ***plain and ordinary meaning***") (emphasis added).)

Importantly, in the IPR, neither Vifor nor Dr. Winkler made any mention of the extraneous restrictions of a "mathematically precise" stoichiometric quantity, or that the claimed pH range must be "maintained," which they now ask this Court to read into the claims. (*See* Ex. 2 at *e.g.*, 38-40 (discussing pH limitation), 41-43 (discussing stoichiometric limitation); Ex. 3 at ¶¶ 110-112 (discussing pH limitation); ¶¶ 117-123 (discussing stoichiometric limitation).) On April 14, 2023,

[6] Vifor's IPR Petition identified only the term "hypochlorite is added instant by instant," which is not identified for construction in this *Markman* proceeding. (Ex. 2 at 16-17.)

Vifor formally adopted and incorporated its IPR Petition and the Winkler Declaration into its Initial Invalidity Contentions in this lawsuit. (*See* Ex. 4 at 10 ("Vifor incorporates in its entirety, as though fully set forth herein, Vifor's Petition" and "all accompanying exhibits").)

On April 24, 2023, the USPTO rejected Vifor's IPR, finding that Vifor failed to establish "a reasonable likelihood" of showing invalidity of any of the Asserted Claims. (Ex. 5 at 13-14.)

D. CONSTRUCTION OF THE DISPUTED CLAIM LIMITATIONS

1. Disputed Limitation - "said hypochlorite being added in stoichiometric quantities with respect to the aldehyde end groups"

Term/Phrase	Plaintiff's Construction	Defendant's Construction
"said hypochlorite being added in stoichiometric quantities with respect to the aldehyde end groups" (claim 1)	Plain and ordinary meaning	"hypochlorite being added in 1:1 molar ratio with respect to the aldehyde end group of the sugar"

Consistent with the governing legal principles of claim construction and the intrinsic record, Biofer respectfully submits that this disputed claim term should be given its plain and ordinary meaning to a POSA.

First, and foremost, Biofer's proposed construction should be adopted because claim terms "are generally given their ordinary and customary meaning" which is "the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention." *Phillips*, 415 F.3d at 1312-13. None of the claims, the patent specification or the prosecution history requires deviation from that plain and ordinary meaning. Rather, as Biofer's expert Dr. Paul Chirik explains, the intrinsic record fully supports the plain and ordinary meaning. (*See* Chirik Decl. ¶¶ 26-40.) Indeed, nothing in the claim language invites, let alone requires mathematical precision. *See, e.g., Rembrandt Diagnostics, LP*, 809 F. App'x at 912. Vifor's request that this Court commit

the "cardinal sin" of claim construction by reading such an unrecited limitation into the claim term should be denied. *See Phillips*, 415 F.3d at 1320 and the authorities cited above at pages 5-7.

Vifor's position should also be rejected because a POSA would know and understand that a mathematically precise molar ratio is not even feasible in the context of a chemical reaction involving the claimed polysaccharide dextrins/dextrans, which are not mono-dispersed chemicals. (Chirik Decl. ¶¶ 30-31.) That understanding of a POSA is fully supported and confirmed by the patent specification which describes the stoichiometric calculation as being based on the "average molecular weight" or "dextrose equivalents" value of the sugar, which involves approximation rather than exact mathematical precision. (*See* Ex. 1 at 6:51-59; 7:22-43; Chirik Decl. ¶ 28.) Indeed, POSAs use the "dextrose equivalents" measurement as an approximation for the number of aldehyde end groups, enabling an estimate of the amount of hypochlorite to be added. (Chirik Decl. ¶ 31.) The patent examples further support Biofer's propose construction, including because the examples involving the claimed maltodextrins/dextrans calculate the amount of hypochlorite based on the "average" molecular weight and/or dextrose equivalents value of the sugars, without any mention of an exact mathematically precise 1:1 molar ratio.[7] (*Id.* at ¶ 32; Ex. 1 at, e.g., Examples 5-7.) Therefore, while a POSA would understand how to calculate and add a stoichiometric amount of hypochlorite to the solution, they would also recognize that the claim term could not and does not require a mathematically precise 1:1 molar ratio. (Chirik Decl. ¶ 31.)

Similarly, during prosecution, neither the applicants nor the USPTO Examiner ever referred to the stoichiometric limitation as requiring a mathematically precise 1:1 molar ratio. The applicants merely explained that the purpose was to try to avoid excess hypochlorite and facilitate

[7] Notably, the only reference to a 1:1 molar ratio appears in Example 1, which discusses glucose as the sugar—a sugar which is outside the scope of the patent claims—but does not indicate that mathematical precision is required. (Ex. 1 at 11:11-15; Chirik Decl. ¶ 32.)

selective oxidation of the aldehyde end groups. (Chirik Decl. ¶ 33; Chirik Ex. C at BIOFER_00000273.) Even when distinguishing prior art which suggested using less than "1.2 times" the theoretical stoichiometric amount, the applicants focused on the differences in the prior art reaction, not on any requirement of stoichiometric 1:1 mathematical precision. (Chirik Decl. ¶ 33; Chirik Ex. C at BIOFER_00000271-272, BIOFER_00000315, -320.)

Vifor's position should also be rejected because the law is clear that "a patentee need not define his invention with mathematical precision." *Niazi Licensing Corp. v. St. Jude Med. S.C., Inc*., 30 F.4th 1339, 1347 (Fed. Cir. 2022). Courts consistently reject attempts, like Vifor's, to impose exact mathematical precision on claim terms. *See, e.g., Rembrandt Diagnostics, LP,* 809 F. App'x at 912 (reversing claim construction because it "imposes a mathematical or numerical rigor of exactness that is not supported by the intrinsic evidence"); *Unverferth Mfg. Co. v. Meridian Mfg., Inc*., No. C19-4005-LTS, 2020 WL 1919922, at *12-13 (N.D. Iowa Apr. 20, 2020) (rejecting proposed construction that the terms "vertical," "horizontal," and "parallel" required "mathematical precision"); *Denneroll Holdings Pty Ltd. v. Chirodesign Grp., LLC*, No. 4:15-CV-740, 2016 WL 705207, at *3 (S.D. Tex. Feb. 23, 2016) (rejecting argument that the term "orthogonal" required "mathematical exactitude"); *SCA Tissue N. Am., LLC v. Tarzana Enterprises, LLC*, No. 11-CV-316-BBC, 2011 WL 10985233, at *4-7 (W.D. Wis. Dec. 1, 2011) (recognizing that the claim term "equal" does not require "mathematical precision"); *Int'l E-Z Up, Inc. v. Caravan Canopy Int'l, Inc*, No. CV 01-6530 SVW (CTX), 2002 WL 34536685, at *3 (C.D. Cal. May 14, 2002) (rejecting that the term "parallel" required "mathematical precision").

Accordingly, Biofer respectfully submits that the broad language and ordinary meaning of this claim term to a POSA should control here, and that Vifor's post-IPR attempt to add restrictions to the unencumbered language of the claims, in order to fabricate a non-infringement argument,

find no support in the law or the intrinsic record and should be rejected. *See id*. and the authorities cited on pages 5-7 above.

On this it is worth noting again that Vifor and its expert told the USPTO just a few months ago in its IPR challenge of the Asserted Patent's validity that the claim language at-issue should be given its "plain and ordinary meaning," and then went even further to adopt and incorporate that position in this lawsuit. (*See* Ex. 2 at 16 ("Petitioner's proposed constructions represent the plain and ordinary meaning that a POSA would assign to the claim terms, which are the same constructions that would be appropriate in district court litigation"); Ex. 3 at ¶ 37 ("I have reviewed the claims of the '320 patent and believe that a POSA would understand each of the other claim terms to have their plain and ordinary meaning"); Ex. 4 at 10 ("Vifor incorporates in its entirety, as though fully set forth herein, Vifor's Petition" and "all accompanying exhibits").) In Vifor's "plain and ordinary meaning" construction in the IPR, there was no mention of so-called "mathematical precision." (*See* Ex. 2 at *e.g*., 41-43; Ex. 3 at ¶¶ 117-123.) Now, after losing its IPR validity challenge (*see* Ex. 5), in an effort to avoid infringement,[8] Vifor reverses itself to argue before this Court that the claim term necessitates exact 1:1 molar ratio mathematical precision.[9]

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[8] Within days after losing the IPR, Vifor served a supplemental interrogatory response raising—for the first time—an unexplained assertion of non-infringement of the stoichiometric limitation.

[9] Notably, Vifor's IPR petition and the supporting Declaration of Dr. Winkler contradict its current argument. For instance, Dr. Winkler cited a dictionary definition of "stoichiometry" which does not refer to or require exact mathematical precision. (Ex. 3, ¶ 117, n. 6; Chirik Decl. ¶ 36.) Dr. Winkler also implicitly recognized that exact mathematical precision is not required, "because maltodextrin is a polymer composed of chains of different molecular weights, one cannot directly calculate the number of moles of maltodextrin from the number of grams" and that "maltodextrin quantities are often characterized by their 'dextrose equivalents' (DE), which quantifies the amount of reducing sugar present in a sugar product …." (Ex. 3, ¶ 121; Chirik Decl. ¶ 37) and described "dextrose equivalent ("DE")" as a non-mathematically precise "measure" of the amount of reducing sugar present in a polysaccharide that is "indicative of the average degree of polymerization for sugars." (Ex. 3, ¶ 56; Chirik Decl. ¶ 35.) Finally, Dr. Winkler estimated molar ratios using dextrose equivalents and argued that ranges as low as 0.85 and as high as 1.21 exhibited stoichiometric quantities. (Ex. 3, ¶¶ 117-123; Chirik Decl. ¶ 38.)

During the parties' meet-and-confer on May 3, 2023, Vifor's counsel confirmed that their proposed construction requires precise mathematical accuracy and that such proposed construction is not the plain and ordinary meaning of the claim term. (*See* Ex. 6.) Such blatant mistreatment of the disputed claim language as a nose-of wax in order fabricate a non-infringement position should not be countenanced by this Court. *Ramot at Tel Aviv Univ. Ltd.,* 2020 WL 2517581, at *12.

Biofer respectfully submits that its proposed construction accords with its ordinary meaning to a POSA and should be adopted.

2. Disputed Limitation - "pH between 7.0 and 9.0"

Term/Phrase	Plaintiff's Construction	Defendant's Construction
"pH between 7.0 and 9.0" (claim 1)	"pH range of between 6.8 and 9.2"	"pH is maintained in the interval separating 7.0 and 9.0"

The parties dispute over the meaning of the term "pH between 7.0 and 9.0" in claim 1 is two-fold. First, Biofer's proposed construction is based on the patentee's express definition in the intrinsic record of the prosecution history as to the error range to be applied to the claimed pH values. (Myerson Decl. ¶¶ 35-43.) Secondly, Defendant Vifor, tries to fabricate a post-IPR non-infringement argument, by asking this Court to add unrecited limitations ("maintained in the interval") to the disputed claim language. Once again, Vifor's proposed construction is at-odds with the "plain and ordinary meaning" construction that it presented to USPTO in the IPR (and incorporated into its contentions in this lawsuit (Ex. 4 at 10) which made no mention whatsoever of such additional restrictions. (*Compare* to Ex. 2 at 39-40 and Ex. 3 at ¶¶ 110-112 (no mention by Vifor or its expert of "maintained" or "interval").

With respect to the first dispute over the construction of the pH values themselves, they were expressly defined by the patentee/inventor during prosecution to have an error range of ±0.2. Indeed, as mentioned above, the Marchi Declaration described comparative testing where Example

5 of the Asserted Patent was repeated at a "pH of 8,"—which the applicant expressly defined as a "pH between 7.8 and 8.2"—and at a "pH of 10.0"—which the applicant also expressly defined as a "pH between 9.8 and 10.2." (*See* Myerson Ex. C at BIOFER_00000414-415, ¶¶ 3-4; Myerson Decl. ¶ 36.) Based on this explicit definition in the intrinsic record, a POSA would understand the recited pH values of 7.0 and 9.0 in claim 1 to have that expressly defined error range of ±0.2. (Myerson Decl. ¶ 38.) Notably, Vifor acknowledged the import of the Marchi Declaration in its initial invalidity contentions by acknowledging that for the claimed oxidation step, the pH of 10.0 was equated with "9.8-10.2" and the pH of 8.0 with "7.8 to 8.2." (*See* Ex. 4 at 36.) Biofer respectfully submits that the disputed claim language should be construed to accord with the patentee's explicit definition in the prosecution history. *See TecSec, Inc. v. Int'l Bus. Machines Corp*., 731 F.3d 1336, 1344 (Fed. Cir. 2013) (affirming construction because applicant "defined the term during prosecution"); *Honeywell Int'l, Inc. v. Universal Avionics Sys. Corp*., 493 F.3d 1358, 1364 (Fed. Cir. 2007) (affirming construction where to hold otherwise "would ignore the patentees' definition of the term 'heading' and their consistent use of that term throughout the prosecution history"); *Tempo Lighting, Inc. v. Tivoli, LLC*, 742 F.3d 973, 977 (Fed. Cir. 2014) (affirming construction "inert to light" where applicant defined it in the prosecution history).

The patentee's explicit definition in the intrinsic record of the error range on the oxidation pH values is also consistent with the patent specification and the general knowledge of a POSA with respect to pH variation of measurements. As Dr. Myerson explains in his declaration, a POSA would know and appreciate that various conditions can affect pH measurements. (Myerson Decl. ¶ 43.) Based on potential variance in pH values and measurements (*e.g*., due to conditions such as temperature, equipment, etc.), a POSA would generally regard a tolerance range of ±0.2 for pH measurements as appropriate. (*Id*.) The patent specification is consistent with and confirmatory

of such general knowledge of a POSA, as well as the express definition in the Marchi Declaration. For instance, Examples 5-7 in the Asserted Patent describe the preparation of activated sugars using maltodextrin and dextran (which are sugars covered by the Asserted Claims). In these examples, the inventors consistently refer to pH measurements as including a tolerance of ±0.2 (or even as high as ±0.5).[10] Thus, these disclosures in the specification would affirm the understanding of a POSA from the Marchi Declaration that the claimed range of 7.0 to 9.0 means and encompasses a range of 6.8 to 9.2 based on a tolerance of ±0.2. (Myerson Decl. ¶¶ 42-43.)[11]

Accordingly, Plaintiff's proposed construction of "pH between 6.8 and 9.2," is consistent with the explicit definition and other disclosures in the intrinsic record, and should be adopted because "[t]he customary meaning of a claim term is not determined in a vacuum and should be harmonized, to the extent possible, with the intrinsic record, as understood within the technological

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[10] *See* Ex. 1 at 14:31-32 ("the pH is brought to the value of ***9.0±0.5***"); 14:37-38 ("at ***a pH of 10.8±0.2***"); 14:39-40 ("The cooled solution is brought to pH ***6.0±0.5***"); 15:11-12 ("the pH value is brought to ***11.5±0.2***"); 15:18-19 ("pH 11±0.2"); 15:20-21 ("The pH of the solution is brought to the value of ***6.0±0.2***"); 15:58-59 ("the pH value is brought to ***11.5±0.2***"); 15:66-67 ("pH ***11.5±0.2***"); 16:1-2 ("The pH of the solution is brought to the value of ***6.0±0.2***"); *see also* Myerson Decl. ¶¶ 39-41.

[11] To the extent that Defendant Vifor argues a disclaimer or disavowal of claim scope in connection with the Marchi Declaration and amendment, Plaintiff notes that both the patentee and the USPTO referred interchangeably to the claimed pH value(s) with and without a decimal point during prosecution, such that a POSA would not view the decimal point in the claims as issued to have been narrowing in terms of meaning or scope. (Myerson Decl. ¶ 43 n.1.) Indeed, the claims were initially filed with a decimal point in the claimed range as "7.0 to 9.0" (*id*.; Myerson Ex. C at BIOFER_00000029-31), and then went back and forth to/from "7 to 9" without any decimal (*id*. at BIOFER_00000263-269), and then back to the originally claimed "7.0 to 9.0" range (*id*. at BIOFER_00000350-354), each time without indication of a change in claim scope or meaning. The Examiner likewise interchangeably referenced the same pH values with and without decimal points in the Reasons for Allowance. (Myerson Ex. C at BIOFER_00000441 (referring to the claimed range of 7.0 and 9.0 as a "pH range of 7-9"); *id*. at BIOFER_00000441-442 (referring to pH measurements of 10.0 and 10 interchangeably).) Moreover, in connection with Vifor's unsuccessful challenge to the validity of the '320 patent claims, the USPTO similarly referred to the pH values of 8.0 and 10.0 in the Marchi Declaration interchangeably with 8 and 10. (Ex. 5 at 10-12.) Thus, based on such consistent interchangeable usage, a POSA would not understand the decimal points in the issued claimed range to have been narrowing in scope or meaning.

field of the invention." *Lexion Med., LLC v. Northgate Techs., Inc.*, 641 F.3d 1352, 1356 (Fed. Cir. 2011) (affirming a claim construction that limitation reciting that a gas entering a humidifier "hav[e] a temperature within 2°C of the predetermined temperature" did not require that the temperature entering the humidifier always had to be within the 4 degree range of the predetermined temperature since the specification tolerated some fluctuation).

Finally, with respect to this claim limitation, Defendant's post-IPR attempt to avoid infringement by reading into the claims unstated requirements that the pH must be "maintained in the interval separating" 7.0 to 9.0 once again violates the "cardinal sin" of patent law that limitations should not be read into the claims. *See Phillips*, 415 F.3d at 1320 and the other authorities cited above at pages 6-7. Defendant will likely point to the occasional use of the word "maintaining" in the patent specification in some but not other parts of the specification;[12] however, the claims of a patent are not limited to examples in the specification, even preferred ones.[13] *See Ekchian v. Home Depot, Inc.*, 104 F.3d 1299, 1303 (Fed. Cir. 1997) (finding claims not limited to conductivity levels disclosed in examples, "[w]hile examples disclosed in the preferred embodiment may aid in the proper interpretation of a claim term, the scope of a claim is not necessarily limited by such examples"); *Falana v. Kent State Univ.*, 669 F.3d 1349, 1355 (Fed. Cir. 2012) ("this court has 'cautioned against limiting the claimed invention to preferred embodiments or specific examples in the specification.'") (internal citations omitted).

Here, the claims state only that the pH should be "between 7.0 and 9.0," without specifying any need for "maintaining," so Defendant's proposed post-IPR construction violates the rule

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[12] Again, the pH limitation is discussed in several parts of the specification without use of the word "maintaining." (*See* Ex. 1 at, e.g., 6:30-36; 6:36-43; 7:5-10; 9:9-16; 10:11-19; 10:46-47.)

[13] Defendant's proposed construction also adds the word "interval," which is nowhere to be found in the patent specification. During the parties' meet-and-confer, Defendant confirmed that such wording was not intended to exclude the end points of the range.

against reading limitations into the claims. *See Phillips*, 415 F.3d at 1319-20; *see also Corcept Therapeutics, Inc. v. Teva Pharms. USA, Inc*., No. CV183632SDWLDW, 2020 WL 3425302, at *3 (D.N.J. June 23, 2020) (rejecting argument that the term "achieve mifepristone blood levels greater than 1300 ng/mL" requires that the patient's blood levels "remain" greater than 1300 ng/mL despite references in specification).

Finally, it should be noted that Defendant's proposed construction to this Court is also, once again, inconsistent with its recent position before the USPTO in the IPR—which was then adopted in this lawsuit (Ex. 4 at 10)—*i.e*., that the disputed claim term should receive its plain and ordinary meaning without mention of any extraneous "maintaining in the interval separating" restrictions which Defendant now asks this Court to read into the claims.

Accordingly, Defendant's improper treatment of the claims as a nose-of-wax, and unwarranted restriction on the language of the claims, should be rejected in favor of the broad language of the claim limitation and the express definition of the patentee in the prosecution history. *See, e.g., Ramot,* 2020 WL 2517581, at *12 and the authorities at pages 5-7 above.

IV. CONCLUSION

For at least the reasons stated above, Plaintiff Biofer respectfully submits that its proposed constructions should be adopted by the Court.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on June 12, 2022, I caused the foregoing to be served on the following counsel of record by electronic mail:

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